



Lantana
CONSULTING GROUP



QRDA CATEGORY I R3 CHANGES FROM QRDA CATEGORY I R2

QRDA GC Meeting

Sarah Gaunt
April 8, 2015

Introduction

- QRDA Category 1 R2 Draft Standard for Trial Use (DSTU) was published in July 2012
- The QRDA templates included in the July 2012 DSTU were updated for errata approved as of December 21, 2012 (released February 2013).
- The QRDA templates were again updated for errata approved as of June 27, 2014 (released October 2014).
- QRDA Category 1 R3 DSTU went through ballot in the December 2014 HL7 Ballot period

Project Scope Statement (PSS) (Requirements)

Review Project Scope from PSS:

- The scope of this project is to create a new release update to the Quality Reporting Document Architecture, Release 2, DSTU standard (including published errata updates). The updates of this new release will include:

PSS: Align with QDM 4.1.x

1. Update templates to align with the Quality Data Model (QDM) version 4.1, which was published in July 2014.

- Remove (retire) QRDA templates where corresponding QDM data elements have been removed
 - Add QRDA templates where QDM data elements have been added
 - Remove (retire) QRDA elements/templates where QDM attributes have been removed
 - Add QRDA elements/templates where QDM attributes have been added
 - Analyze changed QDM data elements/attributes and make needed modifications to existing QRDA templates
- **NOTE: One of the ballot comments suggested aligning with QDM 4.1.2 which was published in January 2015. This comment was approved, thus QRDA R3 is aligned with 4.1.2**

PSS: QRDA I R2 DSTU Comments

2. Review and triage the QRDA Category I, Release 2 DSTU comments that were considered as New Feature Requests, determine whether they are appropriate for inclusion in Release 3 and then update the implementation guide accordingly.

PSS: Align with C-CDA R2

3. Review the Consolidated CDA (C-CDA) templates that were used in the QRDA-I, R2, and where applicable; update the templates to align with the C-CDA R2 templates.
 - Version any template based on a C-CDA R2 template that has been versioned and update to align with any new requirements
 - Analyse new C-CDA R2 templates to determine if they can be used as a base for existing or new QRDA templates

QRDA Category I R3 Ballot Reconciliation (1)

Overall Votes:

- Affirmative: 30
- Negative: 26
- Abstain: 66
- No vote: 19

There were a total of 143 ballot comments with the following breakdown:

- 86 affirmative comments (typos, questions, comments and suggestions)
- 57 negative comments

QRDA Category 1 R3 Ballot Reconciliation (2)

- All comments were reconciled and voted on by HL7's Clinical Quality Information (CQI) workgroup by mid-March 2015
- The final ballot reconciliation spreadsheet was approved by CQI on 27th March 2015
- All negative commenters have been formally requested to withdraw their negative votes

High-Level Changes: Overview

The following slides present a very high-level overview of the changes to the templates in QRDA Category I R3 covering changes of note of the following types:

- Versioning
- Guidance
- General (miscellaneous)
- Alignment with QDM 4.1.2
- Alignment with C-CDA R2
- DSTU Comments

High-Level Changes: Versioning (1)

Templates have been versioned for a number of reasons:

- where a modification has been made to the template
- where the implied template has been versioned
- where contained templates have been versioned
- versioning a template at the bottom of a hierarchy causes a bubble-up effect; all the way to the top of the tree, each containing template will be versioned

High-Level Changes: Versioning (2)

- Where a template has been versioned, "(V2)" has been suffixed to the name of that template (e.g.: Device Allergy (V2)).
- A versioned template's OID remains the same
- Where a template has been versioned, the extension "2014-12-01" (representing the month in which the IG was first released for ballot) has been added to the template identifier.
- Where a template has been versioned, a constraint for `templateId/extension="2014-12-01"` has been added.
- Where contained templates have been versioned, references to those templates have been updated.

High-Level Changes: Versioning (3)

Example:

3.50.1 Device Applied (V2) - Draft

[procedure: identifier urn:h17ii:2.16.840.1.113883.10.20.24.3.7:2014-12-01
(open)]

5. **SHALL** contain exactly one [1..1] `templateId` (CONF:1140-12391) such that it
 - a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.24.3.7"` (CONF:1140-12392).
 - b. **SHALL** contain exactly one [1..1] `@extension="2014-12-01"` (CONF:1140-27132).

High-Level Changes: Guidance

- Added guidance to the description of each QRDA entry-level template stating which QDM datatype is represented by the template (e.g.: *"This template represents the QDM datatype: Device, Adverse Event."*)
- Added guidance to the description of templates where needed around QDM attributes: Start Datetime and Stop Datetime.
- All examples in the IG have been updated to add more guidance to implementers around QDM attributes.

High-Level Changes: General (misc.) (1)

- Removed constraints where such constraints were already stated in the implied template. There are two exceptions to this:
 - classCode and moodCode have historically been repeated in the implying template
 - where it has been determined that repeating a constraint (such as negationInd) adds clarity for implementers, these constraints have been repeated
- Added "SHALL contain exactly one [1..1] @sdtc:valueSet" to relevant coded elements.
- Where an author participant was explicitly spelled out in a template in the previous version, this has been replaced with a reference to the C-CDA Author Participation template.

High-Level Changes: General (misc) (2)

Updated incorrectly entered constraints (no change to meaning of constraint, improves clarity)

- Incorrect:

SHALL contain exactly one [1..1] **code** (CONF:16385).

- a. This code **SHALL** contain exactly one [1..1] **@code="ASSERTION"** Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4 **STATIC**) (CONF:16386).

- Correct:

SHALL contain exactly one [1..1] **code** (CONF:1140-16385).

- a. This code **SHALL** contain exactly one [1..1] **@code="ASSERTION"** Assertion (CONF:1140-16386).
- b. This code **SHALL** contain exactly one [1..1] **@codeSystem="2.16.840.1.113883.5.4"** (CodeSystem: ActCode urn:oid:2.16.840.1.113883.5.4 **STATIC**) (CONF:1140-27575).

High-Level Changes: Align with QDM 4.1.2 (1)

Remove (retire) QRDA templates where corresponding QDM datatypes/attributes have been removed:

- Diagnostic Study Result
- Functional Status Result
- Intervention Result
- Laboratory Test Result
- Patient Characteristic Estimated Date of Conception
- Patient Characteristic Gestational Age
- Physical Exam Finding
- Procedure Result

High-Level Changes: Align with QDM 4.1.2 (2)

Add QRDA templates where QDM data elements/attributes have been added:

- Fulfills General Relationship Operator
 - Added CDA extension inFulfillmentOf1 to be able to create this new template

High-Level Changes: Align with QDM 4.1.2 (3)

Version templates and make required modifications to existing QRDA templates

- Added various attributes to various templates (see high-level change log in Volume 1 of IG for more details):

- | | | |
|----------------------|-----------------------|----------------------|
| • Target Outcome | • Provider Preference | • Negation Rationale |
| • Anatomical | • Severity | • Dose |
| • Location Site | • Status | • Frequency |
| • Anatomical | • Method | • Route |
| • Approach Site | • Result | • Active Datetime |
| • Laterality | • Cause | • Signed Datetime |
| • Ordinality | • Start/Stop Datetime | • Radiation Duration |
| • Patient Preference | • Refills | • Radiation Duration |

High-Level Changes: Align with QDM 4.1.2 (4)

Version templates and make required modifications to existing QRDA templates

- Removed various attributes from various templates (see high-level change log in Volume 1 of IG for more details):
 - Reason
 - Transfer From
 - Transfer To

High-Level Changes: Align with QDM 4.1.2 (5)

Version templates and make required modifications to existing QRDA templates

- Diagnosis Family History
 - In QRDA R2 the QDM datatype Diagnosis, Family History represented by Diagnosis Family History - a specialization of C-CDA R1.1 Family History Organizer template
 - Family History Organizer template contains Family History Observation template
 - Because QRDA Diagnosis Family History template is a specialization of the Family History Organizer template it also contains the Family History Observation template and uses it as-is with no further constraints
 - QDM 4.1.2 adds QDM attributes Ordinality, Patient Preference, Provider Preference, Severity and Status to the QDM datatype Diagnosis, Family History
 - These attributes need to be added to the Family History Observation and in order to add them, this template needed to be specialized for QRDA R3
 - The new QRDA R3 Diagnosis Family History Observation template was added and is contained by the QRDA R3 Diagnosis Family History (V2) template

High-Level Changes: Align with QDM 4.1.2 (5)

Version templates and make required modifications to existing QRDA templates

- Transfer To/Transfer From
 - In QRDA R2 the QDM data types Transfer To and Transfer From were represented by CDA Participation templates
 - QDM 4.1.2 requires that Transfer To and Transfer From contain Patient Preference and Provider Preference.
 - A CDA Participation cannot contain entry-level templates
 - In QRDA R3 the participations have been wrapped in Encounter templates and the Encounter templates are called Transfer To (V2) and Transfer From (V2)

High-Level Changes: Align with C-CDA R2 (1)

Version any QRDA template based on (conforms to) a C-CDA R2 template that has been versioned from C-CDA R1.1

- The majority of C-CDA templates implied by QRDA templates have been updated and are on V2
- These QRDA templates have all been updated to imply the new versions of the C-CDA templates

High-Level Changes: Align with C-CDA R2 (2)

Update QRDA templates based on (conforms to) a C-CDA R2 template to align with new requirements:

- Changed from SNOMED to LOINC where necessary (e.g. C-CDA R2 Problem Observation now uses LOINC for code element rather than SNOMED – this affects QRDA Diagnosis and Symptom templates)
- C-CDA R2 “planned” type templates now constrain statusCode to “active” – removed statusCode=“new” constraints from implying templates (e.g. QRDA Order and Recommended templates)

High-Level Changes: Align with C-CDA R2 (3)

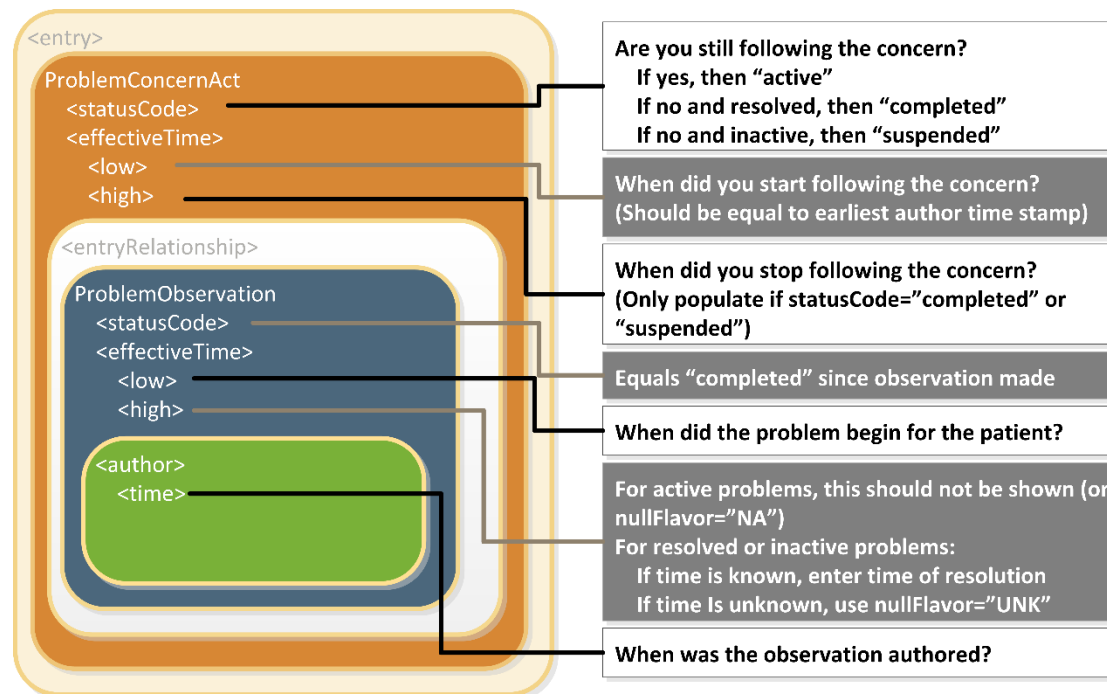
Update QRDA templates based on (conforms to) a C-CDA R2 template to align with new requirements:

- Diagnosis and Symptom (Active, Inactive and Resolved) templates
 - In QRDA R2 the Diagnosis and Symptom (Active, Inactive and Resolved) templates used the QRDA templates Problem Status Active, Problem Status Inactive and Problem Status Resolved templates to indicate status.
 - These three Problem Status templates were specializations of the C-CDA R1.1 Problem Status template.
 - In C-CDA R2 the Problem Status template has been deprecated.
 - In C-CDA R2 the new way of indicating status is to wrap the Problem Observation template in a Problem Concern Act template and to use a combination of both templates' statusCode, effectiveTime and time elements.
 - In QRDA R3 we have followed this pattern and each specialization of the C-CDA R2 Problem Observation (V2) template (Diagnosis Active, Diagnosis Inactive, Diagnosis Resolved, Symptom Active, Symptom Inactive and Symptom Resolved) is now contained in a specialization of the C-CDA R2 Problem Concern Act template (Diagnosis Active Concern Act, Diagnosis Inactive Concern Act, Diagnosis Resolved Concern Act, Symptom Active Concern Act, Symptom Inactive Concern Act and Symptom Resolved Concern Act).

High-Level Changes: Align with C-CDA R2 (3)

Update QRDA templates based on (conforms to) a C-CDA R2 template to align with new requirements:

- Diagnosis and Symptom (Active, Inactive and Resolved) templates
 - The following diagram shows how the new pattern works:



High-Level Changes: DSTU Comments (1)

- Added guidance to the description of each relevant template around how to implement the QDM attribute Negation Rationale: *"QDM attribute: Negation Rationale is represented by setting negationInd="true" and stating the reason (rationale) in a contained Reason (V2) template. Although Reason (V2) is not explicitly contained in every template, it is available for use in any template."*
- Added constraint "MAY contain zero or one [0..1] @negationInd" (where it was missing), to each relevant template for implementation of the QDM attribute Negation Rationale.
- Added guidance on using translation where there are vocabulary mismatches between C-CDA and QRDA

High-Level Changes: DSTU Comments (2)

“NOT DONE” issue

- We want to state that something did not occur for a specific reason; e.g.:
 - a procedure was not performed
 - a test was not done
 - a medication was not administered
- We cannot use a specific code because we want to exclude **all** possibilities, not just that of a single formulation or specific procedure; e.g.
 - “no Antibiotic Medications for Pharyngitis” (general) compared to “no Amoxicillin 60 MG/ML Oral Suspension” (specific)
 - “no Hepatitis A Antigen Test” (general) compared to “no Hepatitis A virus Ab [Units/volume] in Serum by Immunoassay” (specific)

High-Level Changes: DSTU Comments (3)

“NOT DONE” issue

- QRDA uses VSAC value sets
- Each of these value sets is identified by an OID
- e.g.; The value set “Antibiotic Medications for Pharyngitis” has a value set OID of “2.16.840.1.113883.3.464.1003.196.12.1001”
- If we want to state that “No antibiotic medications for Pharyngitis were administered” we are now able to do this using the solution that was decided upon in San Antonio.

High-Level Changes: DSTU Comments (4)

“NOT DONE” issue QRDA solution

1. Set containing act attribute
`negationInd= "true"`
2. Set code attribute
`nullFlavor="NA"`
3. Set code attribute
`sdtc:valueSet="[VSAC value set OID]"`
4. In the originalText element put
`<originalText>None of value set:[value set name]</originalText>`

High-Level Changes: DSTU Comments (5)

“NOT DONE” issue QRDA example

1. Set containing act attribute

`negationInd= "true"`

2. Set code attribute

`nullFlavor="NA"`

3. Set code attribute

`sdtc:valueSet="2.16.840.1.113883.3.464.1003.196.12.1001"`

4. In the originalText element put

`<originalText>None of value set: Antibiotic Medications for Pharyngitis</originalText>`

High-Level Changes: DSTU Comments (6)

“NOT DONE” issue QRDA example XML

```
<entry>
  <!--Medication administered not done,
    patient refusal: Drug declined by patient - reason unknown.
    No "Antibiotic Medications for Pharyngitis" were administered -->
  <act classCode="ACT" moodCode="EVN" negationInd="true">
    ...
    <consumable>
      <manufacturedProduct classCode="MANU">
        ...
        <manufacturedMaterial>
          <code nullFlavor="NA"
            sdtc:valueSet="2.16.840.1.113883.3.464.1003.196.12.1001">
            <originalText>None of value set: Antibiotic Medications for Pharyngitis</originalText>
          </code>
        </manufacturedMaterial>
      </manufacturedProduct>
    </consumable>
    ...
  </act>
</entry>
```

The diagram highlights four specific XML elements with callouts:

- 1: `negationInd="true"` in the `<act>` element.
- 2: `nullFlavor="NA"` in the `<code>` element.
- 3: `sdtc:valueSet="2.16.840.1.113883.3.464.1003.196.12.1001"` in the `<code>` element.
- 4: `<originalText>None of value set: Antibiotic Medications for Pharyngitis</originalText>` in the `<code>` element.

Versioned Template Change View: Trifolia

- Once QRDA Category I R3 has been published it will be possible to log into Trifolia and view an inline change log to see the changes from the previous version of the template you are viewing:

Constraints

Samples

Relationships

Changes

From: Encounter Order (urn:oid:2.16.840.1.113883.10.20.24.3.22)

☒ Inline ☐ List

1. SHALL contain exactly one [1..1] @classCode="ENC" Encounter (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:1140-27534).
2. **SHALL contain exactly one [1..1] @moodCode="RQO" Request (CodeSystem: ActMood urn:oid:2.16.840.1.113883.5.1001 STATIC)**
3. SHALL contain exactly one [1..1] templateId
 1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.24.3.22"
 2. SHALL contain exactly one [1..1] @extension="2014-12-01" (CONF:1140-27064).
4. ~~SHALL contain exactly one [1..1] statusCode (CONF:67-11937):~~
 1. This statusCode ~~SHALL contain exactly one [1..1] @code="new" (CodeSystem: ActStatus urn:oid:2.16.840.1.113883.5.14 STATIC) (CONF:67-11938):~~
5. SHALL contain exactly one [1..1] code
 1. This code SHALL contain exactly one [1..1] @sdct:valueSet (CONF:1140-27623).

IG Change Logs

- **There are two Change Logs in the IG**
 - Volume 1 contains a high-level change log that summarizes the changes for each template
 - Volume 2 contains a detail change log that shows every change for each template

Questions?